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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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HM22/0911

EXAMINER

STUCKER, J

ART UNIT

PAPER NUMBER

164B

**DATE MAILED:** 09/11/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	Examiner	Group Art Unit	

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

#### Status

- Responsive to communication(s) filed on 8/21/01.
- This action is FINAL.
- Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

#### Disposition of Claims

- Claim(s) 1-8 & 13-25 is/are pending in the application.
- Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- Claim(s) \_\_\_\_\_ is/are allowed.
- Claim(s) 1-8 & 13-25 is/are rejected.
- Claim(s) \_\_\_\_\_ is/are objected to.
- Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

#### Application Papers

- See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.
- The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- The specification is objected to by the Examiner.
- The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119 (a)-(d)

- Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- All  Some\*  None of the CERTIFIED copies of the priority documents have been received.
- received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
- received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

#### Attachment(s)

- |  |   |
|--|---|
| <input type="checkbox"/> Information Disclosure Statement(s), PTO-1449, Paper No(s). _____ | <input type="checkbox"/> Interview Summary, PTO-413                     |
| <input type="checkbox"/> Notice of Reference(s) Cited, PTO-892                             | <input type="checkbox"/> Notice of Informal Patent Application, PTO-152 |
| <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review, PTO-948           | <input type="checkbox"/> Other _____                                    |

#### Office Action Summary

The request filed on 8/21/01 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/511582 is acceptable and a CPA has been established. An action on the CPA follows. Claims 1-8 and 13-25 are pending and rejected.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The abstract of the disclosure is objected to because it lacks critical details of the claimed invention such as the composition and chemical structure of the adjuvant. Correction is required. See MPEP § 608.01(b).

The rejection of claims 2-8 and 13 under 35 U.S.C. § 112, second paragraph, for lacking an antecedent basis for "substances" is withdrawn in view of the amendment to claim 1.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 7, 15, 21, and 23 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite by the wording "that enhances the effect medicinal substances". Inserting "of" after "effect" would clarify this claim.

Claims 7, 15, 21, and 23 are vague and indefinite because it is not clear how much time can elapse before administration of the adjuvant after the administration of "the substance" would fall within the boundaries of the instant claims.

Claim 25 is indefinite because the singular article before "nasal" does not agree with the plural "drops".

Claims 2-8, 13-16 and 18-25 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claims, or amend the claims to place the claims in proper dependent form, or rewrite the claims in independent form.

Claims 8 and 25 do not further limit the independent claims because the limitation of "are intended for administration as

a[sic] nasal drops/spray" is an intended use and does not describe or limit the structure of the composition.

The route of administration, timing, antigen, etc., are also intended uses and do not describe or limit the structure of the claimed composition comprising a branched  $\beta$ -1,3 glucan that contains  $\beta$ -1,3-linked side chains anchored by a  $\beta$ -1,6-linkage to the  $\beta$ -1,3-linked chains composition.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4-8, and 13-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for viral vaccines, does not reasonably provide enablement for non-vaccine medicinal substances. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

There is nothing in the art that would indicate that the claimed adjuvant compound, or similar compounds, would enhance the activity of non-immunogenic compositions. That is, one would

expect that this compound, in conjunction with an immunogen, would induce an immune response but there is no expectation that the adjuvant would enhance any physiological reaction except for an immune response to an immunogen. See paper No. 4.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8 and 13-25 are rejected under 35 U.S.C. § 102(b) as being anticipated by Benach et al.

The claims are directed to an adjuvant composition comprising a branched  $\beta$ -1,3 glucan that contains  $\beta$ -1,3-linked side chains anchored by a  $\beta$ -1,6-linkage to the  $\beta$ -1,3-linked chains. The limitations of "enhancing the effect" is an inherent property of the adjuvant composition conveyed by the chemical structure of the adjuvant. The limitation of "a medicinal substance" or "an influenza virus vaccine onto mucosal surfaces" are intended uses and confer no limitation on the structure of the adjuvant composition. Likewise, the limitations of the dependent claims do not further limit the composition or structure of the claimed adjuvant composition.

Applicant's arguments have been fully considered but are not deemed to be persuasive. Applicant argues that the reference does not teach a branched  $\beta$ -1,3 glucan that contains  $\beta$ -1,3-linked side chains anchored by a  $\beta$ -1,6-linkage to the  $\beta$ -1,3-linked chains. This is not convincing as the adjuvant of the reference has the same origin as the claimed adjuvant and would inherently comprise molecules having the claimed structure. It is noted that the claims use open language and are not limited to  $\beta$ -1,3-linked side chains anchored by a  $\beta$ -1,6-linkage to the  $\beta$ -1,3-linked chains. Therefore, the instant invention is anticipated by Benach et al.

Claims 1-8 and 13-25 are rejected under 35 U.S.C. § 102(b) as being anticipated by Takahashi et al.

The claims are directed to an adjuvant composition comprising a branched  $\beta$ -1,3 glucan that contains  $\beta$ -1,3-linked side chains anchored by a  $\beta$ -1,6-linkage to the  $\beta$ -1,3-linked chains. The limitations of "enhancing the effect" is an inherent property of the adjuvant composition conveyed by the chemical structure of the adjuvant. The limitation of "a medicinal substance" or "an influenza virus vaccine onto mucosal surfaces" are intended uses and confer no limitation on the structure of the adjuvant composition. Likewise, the limitations of the dependent claims do not

further limit the composition or structure of the claimed adjuvant composition.

Applicant's arguments have been fully considered but are not deemed to be persuasive. Applicant argues that the reference does not teach a branched  $\beta$ -1,3 glucan that contains  $\beta$ -1,3-linked side chains anchored by a  $\beta$ -1,6-linkage to the  $\beta$ -1,3-linked chains. This is not convincing as the adjuvant of the reference has the same origin as the claimed adjuvant and would inherently comprise molecules having the claimed structure. Takahashi et al. does teach 1,6 side chains, see the table and column 1, line 16, as well as elsewhere, thereby meeting the limitation of the claims. It is noted that the claims use open language and are not limited to  $\beta$ -1,3-linked side chains anchored by a  $\beta$ -1,6-linkage to the  $\beta$ -1,3-linked chains. Therefore, the instant invention is anticipated by Takahashi et al.

Claims 1-8 and 13-25 are rejected under 35 U.S.C. § 102(b) as being anticipated by Rorstad et al. (5,401,727).

The claims are directed to an adjuvant composition comprising a branched  $\beta$ -1,3 glucan that contains  $\beta$ -1,3-linked side chains anchored by a  $\beta$ -1,6-linkage to the  $\beta$ -1,3-linked chains. The limitations of "enhancing the effect" is an inherent property of the adjuvant composition conveyed by the chemical structure of the

adjuvant. The limitation of "a medicinal substance" or "an influenza virus vaccine onto mucosal surfaces" are intended uses and confer no limitation on the structure of the adjuvant composition. Likewise, the limitations of the dependent claims do not further limit the composition or structure of the claimed adjuvant composition.

Rorstad et al. teach the same yeast extracted glucopyranose polymer immunostimulant compound as is instantly claimed. See the abstract and at the bottom of column 4. The reference teaches that this glucan composition is an effective immunostimulant. Therefore, the instant invention is anticipated by Rorstad et al.

No claims are allowed.

Papers related this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).

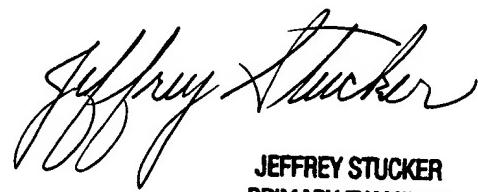
The Group 1600 Fax numbers are: (703) 308-4242 and (703) 305-3014.

Unofficial communications may be faxed to: (703) 308-4426.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Stucker whose telephone number is (703) 308-4237. The examiner can normally be reached Monday to Thursday from 7:00am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



JEFFREY STUCKER  
PRIMARY EXAMINER